

Response Under 37 CFR 1.116

Expedited Procedure

Examining Group 1600

Application No. 09,743,781

Paper Dated: September 28, 2004

In Reply to USPTO Correspondence of June 1, 2004

Attorney Docket No. 4303-030806

REMARKS

Claims 1-3 are currently pending in this application. Claims 1 and 3 have been amended. Support for the language “and other vascular-related diseases or disorders, such as cerebral amyloid angiopathy, vascular amyloidosis, hypertension or vasospasm associated with severe post-traumatic head injury” can be found on page 9, lines 4-5 and page 11, lines 8 and 13-14. Support for the language “0.1 ng to 10 mg/kg body weight/day” can be found on page 15, lines 8-9. No new matter has been added. In view of these amendments and of the following remarks, Applicants believe that all the asserted rejections are in condition for withdrawal and all the claims are in condition for allowance.

Claims 1 and 3 stand rejected under 35 U.S.C. 112, first paragraph, for purported lack of a written description. The Examiner asserts that there does not appear to be enough description in the specification for the limitation “related disorders” in the claims. Additionally, claims 1 and 3 stand rejected under 35 U.S.C. 112, second paragraph, for purported indefiniteness. The Examiner asserts that the specification fails to define what is encompassed by the phrase “related disorder,” in claim 1 and that there is insufficient antecedent basis for the limitation “the soluble A β pro-inflammatory pathway” in line 2 of claim 3.

Claim 1 has been amended to delete the phrase “and related disorders” and to add the specific disorders, “cerebral amyloid angiopathy,” “vascular amyloidosis,” “hypertension” and “vasospasm associated with severe post-traumatic head injury.” These disorders can be found in the specification on page 9, lines 4-5 and page 11, lines 8 and 13-14. Claim 3 has been amended to substitute “a” for “the” in line 2. Based on these amendments, these rejections of the claims are now obviated.

Claims 1 and 3 stand rejected under 35 U.S.C. 102(e) for purported anticipation by Cheng et al. The Examiner states that Cheng et al. disclose a method for treating disorders, such as Alzheimer's disease, by administering to a patient in need thereof an effective amount of a p38 MAP kinase inhibitor.

Applicants respectfully point out that the critical feature of the present invention is the novel discovery that administration of low doses of phospholipase A2 inhibitors have a

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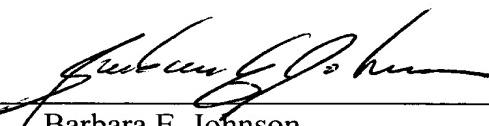
significant effect on diseases or disorders which specifically are characterized by enhanced beta-amyloid-induced vasoactivity, i.e., vasospasm. The underlying mechanism by which this effect arises, i.e., antagonizing a particular pro-inflammatory pathway, is incidental to this discovery. Applicants submit that, in contrast to the claimed invention, Cheng et al. disclose administering a p38 MAP kinase inhibitor to treat all types of inflammatory diseases, and do not specifically teach or suggest a method of modifying beta-amyloid-induced vasoactivity in order to treat specifically vascular-related diseases or disorders, such as Alzheimer's disease, cerebral amyloid angiopathy, vascular amyloidosis, hypertension or vasospasm associated with severe post-traumatic head injury. Moreover, Cheng et al. teach administering such inhibitors in dosages ranging from about 100 µg to 50 mg/kg body weight/day - ranges that are up to five times higher than the claimed invention. Applicants therefore submit that the novel finding of the claimed invention is neither taught nor suggested by the general teachings of Cheng et al.

For all the foregoing reasons, claims 1-3 are patentable over the cited prior art and in condition for allowance. Reconsideration of the rejections and allowance of pending claims 1-3 are respectfully requested.

Respectfully submitted,

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